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Translation

Actemra®, a Treatment for Rheumatoid Arthritis Obtained Approval for Subcutaneous Injection Formulation

March 25, 2013 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku Tokyo; Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that the subcutaneous injection formulation of the humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody, "Actemra®162mg Syringe for SC Injection" and "Actemra®162mg Auto-Injector for SC Injection" [generic name: tocilizumab (genetical recombination)] obtained approval by the Japanese Ministry of Health, Labour and Welfare for "rheumatoid arthritis that does not respond sufficiently to one or more existing therapies (including inhibition of structural joint damage)," on March 25, 2013.

Actemra®, the first antibody drug (humanized monoclonal antibody) originating from Japan, was created by Chugai in collaboration with Osaka University, utilizing genetic recombinant technology to produce a monoclonal antibody against the anti-IL6 receptor. It works by inhibiting biological activity of IL-6 through competitively blocking the binding of IL-6 to its receptor.

A phase III clinical study conducted in Japan has demonstrated non-inferiority of efficacy by subcutaneous formulation comparing to intravenous formulation of Actemra®. The clinical safety profile of the subcutaneous formulation was consistent in nature with that observed with the intravenous formulation.

Rheumatoid arthritis is a systemic inflammatory disease for which the cause is unknown. It appears more commonly in females in their 40s and 50s. The disease causes serious psychological and social problems not only for the patients but also for their families, and measures to counter the disease are seriously needed.

Subcutaneous formulation does not require long time infusion compared to intravenous formulation, does not need to provide infusion facilities, and can be administered at home by self-injection. In combination with the already approved intravenous infusion, the subcutaneous injection will offer additional treatment options so that individual patient can choose an administration route that suits their life style, contributing to improved convenience.

In Japan, Actemra® was first launched with intravenous formulation in June 2005 by Chugai for Castleman's disease, following approval in April 2005. Subsequently, it was approved for the additional indications of rheumatoid arthritis (including prevention of structural damage of joints),

polyarticular-course juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis (sJIA) in April 2008.

With intravenous formulation, in the EU, approval was granted as brand name RoActemra® in January 2009 for the treatment of adult rheumatoid arthritis in people who have either responded inadequately to, or who were intolerant to, previous therapy with one or more DMARD or TNF inhibitors. In the US, in January 2010, Actemra® was approved as the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies, and the indication was expanded in October 2012 to "the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARD".

Currently Actemra® intravenous formulation is approved in more than 100 countries including the US, EU, India, Brazil, Switzerland and Australia. It was also approved in US in April 2011 and in EU in August 2011, for the treatment of active sJIA in patients two years of age and older.

The subcutaneous formulation was submitted in US and Europe in December 2012.

Chugai focuses on bone and joint diseases area as one of the strategic domains, and hopes to contribute to the treatment by providing new therapeutic options for patients and medical professionals.